K091729

1 of 2

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Appendix 1-F: Special 510(k) Summary of Safety and Effectiveness

1. Applicant

BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126
Ph: 262-835-3300
Fax: 262-835-3330

Contact: Lori Hays

2. Date Prepared

June 16, 2008

3. Device Name

Trade Name: GFX Nerve Ablation System

Common Name: Lesion Probe and Generator System

Classification Name(s): Radiofrequency Lesion Probe (21 CFR 882.4725; GXI)
Radiofrequency Lesion Generator (21 CFR 882.4400; GXD)

3. Indications for Use

The Lesion Probe and Generator system is intended to create radiofrequency (RF) heat lesions in nerve tissue. It is intended for use only by trained clinicians in a hospital or clinical setting.

4. Product Description

The GFX Nerve Ablation System provides a minimally invasive technique for creating a neural lesion inhibiting the function of the target nerve. The Generator and probe are used as a system to both stimulate the nerve for the purpose of locating the probe correctly and to create a neural lesion to inhibit nerve function through the application of RF energy. The GFX Nerve Ablation probes are single use devices supplied sterile to the customer.

5. Substantial Equivalence

The following are the predicate devices that are substantially equivalent to the GFX Nerve Ablation System:

510(k) Number: K063753
Device: GFX Nerve Ablation System
BioForm Medical (formerly ACI)
4133 Courtney Rd., Ste. 10
Franksville, WI 53126

510(k) Number: K965182
Device: Radionics RFG-3CF
Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803

6. Summary of Testing

Device integrity and functionality were verified and/or validated using samples produced under routine manufacturing conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

BioForm Medical, Inc.
% Ms. Lori Hays, MT, RAC
Director, Regulatory Affairs
4133 Courtney Road, Suite 10
Franksville, Wisconsin 53126

Re: K081729
Trade/Device Name: GFX Nerve Ablation System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD
Dated: July 28, 2008
Received: July 30, 2008

Dear Ms. Hays:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 1-E: Statement of Indications for Use

510(k) Number (if known): _____

Device Name: GFX Nerve Ablation System

Indications for Use:

The Lesion Probe and Generator system is intended to create radiofrequency (RF) heat lesions in nerve tissue. It is intended for use only by trained clinicians in a hospital or clinical setting.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081729